

CLAIMS

1. A nucleic acid amplification assay for quantitative and/or qualitative analysis of the presence of a specific analyte or specific analytes in a biological sample, which analytes, if present, are contained in biological particles (4) of said sample (2), in which assay the sample (2) is forced in a first direction through a filter (6) that retains said biological particles (4) **characterised** in that said biological particles (4) retained in said filter (6) are flushed, by a flush flow (8), in a second opposite direction through said filter (6) out of said filter (6) and said flush flow (8) containing said biological particles (4) flushed out is analysed for the analyte or analytes.
2. The assay of claim 1 **characterised** in that said assay comprises an additional filtration prior to the filtration retaining the biological particles (4) containing the analyte or analytes, which additional filtration does not retain the biological particles (4) containing the analyte or analytes but retains particles (10) that might interfere with the analysis of the analyte or analytes.
3. The assay of claim 1 or 2 **characterised** in that the flow containing the biological particles (4) containing the analyte or analytes flushed out is analysed for the analyte or analytes without any further purification.
4. The assay of claim 1, 2 or 3 **characterised** in that retention of the biological particles (4) containing the analyte or analytes in the filter (6) is essentially size dependent.
5. The assay of any of claims 1 to 4 **characterised** in that retention of the biological particles (4) containing the analyte or analytes in the filter (6) is essentially dependent on the chemical properties of the particle.
6. The assay of any of claims 1 to 5 **characterised** in that the biological particles (4) containing the analyte or analytes are selected from the group consisting of prokaryotic or eukaryotic cells or spores or components thereof, viruses or viral particles, complexes comprising protein and/or nucleic acid, and any combination thereof.

7. The assay of claim 6 **characterised** in that the biological particles (4) containing the analyte or analytes are selected from the group consisting of bacteria, bacterial cell, plant pollen, mitochondria, chloroplast, cell nuclei, virus, phage, chromosome and ribosome.
- 5 8. The assay of any of claims 1 to 7 **characterised** in that the means of analysing the analyte or analytes is selected from the group consisting of polymerase chain reaction (PCR), reverse transcriptase polymerase chain reaction (RT-PCR), ligase chain reaction (LCR), proximity ligation assay, nucleic acid sequence based amplification (NASBA), strand displacement amplification (SDA) and any combination thereof.
- 10 9. The assay of any of claims 1 to 8 **characterised** in that the biological particles (4) containing the analyte or analytes are flushed with a liquid or a gas preferably not contained in the original sample 2.
10. The assay of any of claims 1 to 9 **characterised** in that the analyte or analytes are selected from the group consisting of a living and/or dead cell or virus; a peptide, a protein
15 or complex thereof; a nucleic acid; and any combination thereof.
11. The assay of claim 10 **characterised** in that the analyte or analytes comprises living and/or dead cells and/or viruses selected from the group consisting of a mold, a yeast, a eukaryotic cell or organism, a pathogenic virus and a cancer cell.
12. The assay of claim 10 **characterised** in that the analyte or analytes comprises
20 nucleic acids selected from the group consisting of DNA, RNA and any derivative thereof.
13. The assay of claim 10 **characterised** in that the analyte or analytes comprises peptides and/or proteins or complexes thereof selected from the group consisting of a hormone, a growth factor, an enzyme or parts thereof and/or complexes thereof; and any combination thereof.
- 25 14. An arrangement (12) for preparing a biological sample (2) for quantitative and/or qualitative analysis of the presence of a specific analyte or specific analytes, which

analytes, if present, are contained in biological particles (4) of the sample (2), wherein the arrangement (12) comprises

- a) a housing (14) for a filter (6);
 - b) a filter (6) within said housing (14) for retaining the biological particles (4) containing the analyte or analytes, said filter (6) having two sides,
 - i) a sample inlet side (16) and
 - ii) a flushing flow inlet side (18); and
 - c) means for
 - i) leading (20) the sample (2) through the filter (6) from the sample inlet side (16) to the flushing flow inlet side (18),
 - ii) leading (22) the flush flow (8) from its inlet side (18) to the sample inlet side (16), and
 - iii) retrieving (24) for analysis biological particles (4) containing the analyte flushed from the filter (6);
- 15 **characterised** in that the arrangement (12) comprises a filter rack (32) that is a multi-way valve, with separate connections for sample inlet (20), sample retrieval (24), flush flow inlet (36) and waste disposal (38), and optionally for wash flow (34), and the filter rack (32) with the filter (6) can be turned in alternative positions so that flow is directed from
- d) the sample inlet (20) into the filter (6) from the sample inlet side (16) to the flush flow inlet side (18) and to waste (38) or optionally for use as flush flow,
 - e) the flush flow inlet (22) into the filter (6) from the flush flow inlet side (18) to the sample inlet side (16) and to sample retrieval (24), or
 - f) optionally, the flow inlet (30) into the filter (6) from the sample inlet side (16) to the flush flow inlet side (18) and to waste (38) or for recycling.

15. The arrangement (12) according to claim 14 **characterised** in that the arrangement (12) further comprises

- a) an additional filter (26) that does not retain the biological particles (4) containing the analyte or analytes but retains particles (10) that might interfere with the analysis of the analyte or analytes, and
- b) means for leading (28) the sample (2) through said additional filter (26) prior to leading it through the filter (6) for retaining the biological particles (4) containing the analyte or analytes.

16. The arrangement (12) according to claim 14 or 15 **characterised** in that the arrangement (12) further comprises means for leading (30) a washing liquid or gas through the filter (6) from the sample inlet side (16) to the flushing flow inlet side (18) for washing the retained biological particles (4) containing the analyte or analytes prior to flushing them out of the filter (6).

17. A kit of parts, components and/or reagents for performing the assay according to any of claims 1 to 13, **characterised** in that it comprises the arrangement (12) according to any of claims 14 to 16.